

**United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program**

SOP No.: PDP-ADMIN-06A		Page 1 of 8
Title: USDA/AMS Quality Assurance Unit (QAU)		
Revision: 06	Replaces: 10/01/98	Effective: 07/01/03

1. Purpose:

To establish requirements for the USDA/AMS Pesticide Data Program (PDP) quality assurance unit (QAU).

2. Scope:

This standard operating procedure (SOP) shall be followed by the USDA/AMS PDP QAU located in the Monitoring Programs Office (MPO), Manassas, VA.

3. Outline of Procedure:

- 5.1 Description
- 5.2 Files and Records
- 5.3 Reports
- 5.4 Proficiency Testing (PT) Program
- 5.5 Quality Assurance (QA) Committee
- 5.6 SOPs

4. References:

- PDP QA/Technical Meeting, May 7-9, 2003
 - QA Committee Meeting, May 19-21, 1998
 - QA Committee Meeting, July 9-11, 1996
 - USDA/AMS, EPA/OPP, EPA/OCM Meeting, Minutes, May 21, 1992
 - Jon McNeal, Branch Chief, USDA/AMS Technical Services, Communication to William Franks, Jr., May 8, 1991
 - U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, August 17, 1989
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5. Specific Procedures:

5.1 Description

- a. USDA/AMS shall have a QAU which shall be responsible for monitoring overall quality assurance (QA) of the program. The QAU shall be responsible for assuring USDA/AMS management that facilities, equipment, personnel, methods, practices, records, and controls of the program are in conformance with the plans and SOPs issued by USDA/AMS and all applicable Good Laboratory Practices (GLP) regulations.
- b. The QAU shall be entirely separate from and independent of participant personnel engaged in the technical direction and/or conduct of the residue studies. The QAU shall report directly to the USDA/AMS Technical Director.
- c. The QAU may consist of one or more personnel of suitable qualifications.
- d. The QAU shall maintain records appropriate to PDP residue studies.

5.2 Files and Records

- a. The QAU shall maintain a copy of the PDP annual, semi-annual, or quarterly plan including the schedule of samples, chemicals, and commodities to be tested.
 - b. The QAU shall maintain copies of special project status reports [e.g., supercritical fluid extraction (SFE), GC/MS/MS] prepared by USDA/AMS liaison chemists.
 - c. The QAU shall maintain copies of all semi-annual internal laboratory QA status and yearly audit reports.
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- d. The QAU shall maintain a schedule of USDA/AMS sampling and laboratory reviews and report submissions. This shall include the dates reviews were made and the dates findings were reported to appropriate individuals.
- e. The QAU shall maintain copies of all USDA/AMS sampling and laboratory review reports.
- f. The QAU shall maintain copies of all validation/evaluation data review reports.
- g. The QAU shall maintain copies of all USDA/AMS SOPs, including sampling, laboratory, and USDA/AMS internal SOPs.
- h. The QAU shall maintain copies of authorizations for deviations from the USDA/AMS SOPs.
- i. The QAU shall monitor the proficiency of PDP laboratories by control charts or other evaluation tools.
- j. QA documents shall be maintained in a secure manner with reasonable environmental protection from deterioration for the life of the program.

5.3 Reports

- a. The QAU shall keep PDP management informed of current program QA issues and QA Committee activities.
 - b. The QAU shall review all validation/evaluation study reports prepared by USDA/AMS liaison chemists to ensure that consistent policies are applied and shall make recommendations based on findings.
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5.4 Proficiency Testing (PT)Program

In consultation with the Technical Director, the QAU shall oversee the proficiency testing (PT) program. A PT schedule will be included in the PDP semi-annual program plans.

- a. The California Department of Food and Agriculture (CDFA) QAU shall conduct the commodity-specific PT program for fruit and vegetables, grains, and animal tissues. USDA/AMS shall coordinate with the CDFA QAU to develop an annual PT schedule and commodity/analyte profiles for each set. The CDFA QAU shall prepare and distribute PT samples, perform statistical analyses of the reported results, and prepare a detailed report for each set.
 - b. All PDP laboratories analyzing fruit and vegetables under multi-residue testing protocols will participate in the AOAC Pesticide Residues in Fruit and Vegetables Program. Registration/enrollment arrangements will be made by the Monitoring Programs Office (MPO) each fiscal year.
 - c. All PDP laboratories analyzing drinking water will participate in PT sets designed by MPO and administered by a selected commercial vendor.
 - d. The USDA/AMS QAU shall ensure that PT samples are delivered on schedule and reports are prepared in a timely fashion and distributed to appropriate individuals. Distribution shall include the Technical Director and participating laboratory Technical Program Managers and QAUs.
 - e. The QAU shall review PT reports prepared by CDFA and AOAC and prepare reports for PT sets issued by other commercial vendors. The QAU shall submit comments on overall performance to the Technical Director. Comments shall include recommendations as necessary to improve performance.
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5.5 QA Committee

The USDA/AMS QAU shall serve as liaison to the USDA/AMS QA Committee. The committee shall be comprised of three selected members of participant QAOs and shall address program QA issues/concerns.

Each Committee member shall serve a three-year term, with the final year served as the Presiding Member. The Presiding Member shall have sign-off responsibility for USDA/AMS program SOPs developed or revised during their term.

5.6 SOPs

- a. The QAU shall maintain the USDA/AMS PDP SOPs. Refer to PDP-ADMIN-07, section 5.3, for specific details.
- b. The QAU shall ensure that any authorization for deviations from approved program plans or USDA/AMS PDP SOPs does not compromise integrity of data. The QAU shall ensure that precise and technically accurate documentation of such errors/deviations is maintained.

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June 26, 2003

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Revision 6

May 2003

PDP QA/Technical Meeting

- Split from SOP PDP-ADMIN-06 to separate USDA/AMS QAU and laboratory QAU responsibilities
 - Modified scope for consistency with other SOPs
 - Updated references
 - Changed quarterly internal laboratory QA status reports to semi-annual basis
 - Updated PT program specifications
 - Clarified QA Committee service terms
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